

Remarks

Upon entry of the amendment, claims 14-15 and 25-46 will be pending. Claims 1-13 and 16-24 have been canceled without prejudice or disclaimer and Applicants reserve the right to pursue the subject matter of these claims in related applications. New claims 25-46 have been added to expand the embodiments of the provisionally elected group (see below). Support for the newly added claims is found throughout the specification as filed. Specifically, support for new claims 25-46 may be found at, for example, Table 1 at page 160, row 6, as indicated as "Gene No. 12;" Table 2 at page 171 at row 12 for "clone HSSGD52"; page 39, paragraph [0091] to page 41, paragraph [0096]; page 189, paragraph [0402] to page 191, paragraph [0406]; page 191, paragraphs [0408] to [0409]; page 192, paragraph [0411] to page 196, paragraph [0420]; page 196, paragraph [0422] to page 199, paragraph [0431]; page 200, paragraph [0435] to page 201, paragraph [0436]; page 205, paragraph [0450] to page 207, paragraph [0451]; page 225, paragraph [0495] to page 227, paragraph [0497]; page 239, paragraph [0535] to page 243, paragraph [0548]; page 248, paragraph [0565] to page 250, paragraph [0571]; page 270, paragraph [0635] to page 0272, paragraph [0642]; Example 8 at page 423; Example 9 at page 425; Example 10 at page 427; Example 11 at page 429; Example 22 at page 449. Thus, no new matter has been introduced.

Provisional Election with Traverse

The Examiner has required an election under 35 U.S.C. § 121 of one of the following groups:

- I. Claims 1-10, 14, 15 and 21, drawn to an isolated nucleic acid molecule, a vector containing same, a host cell thereof, and a method of recombinantly producing the encoded polypeptide, classified in class 435, subclass 69.1.
- II. Claims 11-12 and 16, drawn to an isolated polypeptide, classified in class 530, subclass 350.
- III. Claim 13, drawn to an isolated antibody, classified in class 530, subclass 387.9.
- IV. Claim 17, drawn to a method for preventing, treating or ameliorating a medical condition with the polynucleotide, classified in class 514, subclass 44.

- V. Claim 18, drawn to a method of diagnosing a pathological condition by determining a mutation in the polynucleotide, classification depending upon the method steps.
- VI. Claim 19, drawn to drawn to a method of diagnosing a pathological condition by determining the expression levels of the polypeptide, classification depending upon the method steps.
- VII. Claim 20, drawn to a method for identifying a binding partner to the polypeptide, classified in class 436, subclass 501.
- VIII. Claim 22, drawn to a method of identifying an activity in a biological assay, classified in class 435, subclass 4.
- IX. Claim 23, drawn to a binding partner, classification depending on the chemical entity made.
- X. Claim 24, drawn to a method for preventing, treating, or ameliorating a medical condition with the polypeptide, classified in class 514, subclass 2.

Paper No. 20061216, page 2. The Examiner contends that the inventions are distinct, each from the other.

In order to be fully responsive, Applicants provisionally elect, *with traverse*, the subject matter of group II, encompassing claims 25 to 46, drawn to a purified polypeptide of SEQ ID NO:108 and clone ID HSSGD52, for further prosecution. Applicants reserve the right to file one or more divisional applications directed to non-elected inventions should the restriction requirement be made final. Additionally, should the present restriction requirement be made final, Applicants retain the right to petition from the restriction requirement under 37 C.F.R. § 1.144.

Applicants respectfully traverse the restriction requirement. Applicants submit that even where two patentably distinct inventions appear in a single application, restriction remains improper *unless* it can be shown that the search and examination of both inventions would entail a “serious burden” (*See* M.P.E.P. § 803). Applicants disagree with the Examiner's assertion that it would impose an undue burden to examine the nucleic acid, polypeptide, antibody, and method claims for the elected clone (HSSGD52) together.

Even assuming, *arguendo*, that groups I-X represent distinct inventions, Applicants submit that to search and examine the subject matter of all the groups for the elected clone together would not be a serious burden on the Examiner. Applicants submit that a search of polynucleotide claims of the invention would provide useful information for examining claims directed to both polynucleotides and the polypeptides encoded by these polynucleotides. In certain claims this is especially true because the polynucleotide

sequence of these claims is defined in part by the polypeptide that the polynucleotide sequence encodes. Further, Applicants point out that, in many if not most publications, where a published nucleotide sequence is an open reading frame, the authors also include, as a matter of routine, the deduced amino acid sequence of the encoded polypeptide.

Moreover, the Examiner included in group I methods of making a polypeptide. *See* Paper No. 20061216, page 2. A search for this invention would absolutely provide information for group II, polypeptides. Thus the restriction between these two inventions should be withdrawn.

Similarly, a search of the polypeptide claims of the invention would clearly provide useful information for the examination of claims directed to antibodies either produced in response to or having affinity for the subject polypeptides. This is because antibodies are frequently defined by the antigens that they are produced in response to and the epitopes to which they bind. Moreover, in many publications where an antibody is described, the antigen that it was produced in response to is also described.

Further, searches of publications directed to polynucleotides and the use of those polynucleotides would clearly be overlapping. This is so because in many, if not most, publications which describe polynucleotides, these molecules are described by their function, characterization and/or expression profile. Thus, a search of polynucleotide claims would also provide the Examiner with art directed to the manner in which the claimed polynucleotides could be used in diagnostic and therapeutic indications.

Moreover, searches of publications directed to polypeptides and the use of those polypeptides would clearly be overlapping. This is so because in many, if not most, publications which describe polypeptides, these molecules are described by their function. Thus, a search of polypeptide claims would also provide the Examiner with art directed to the manner in which the claimed polypeptides could be used to treat disease states.

In view of the above, Applicants submit that the searches for polynucleotides, polypeptides, and antibodies; methods of diagnosing, preventing and treating disease states using the nucleic acids and proteins of the subject invention; methods of identifying a binding partner to a polypeptide of the subject invention; and methods of identifying an activity in a biological assay of the subject invention, for the elected clone would clearly be overlapping. Accordingly, Applicants request that, in view of M.P.E.P. § 803, the claims of groups I to X for the elected clone (HSSGD52), should be searched and examined in the subject application.

Accordingly, Applicants respectfully request that the restriction requirement under 35 U.S.C § 121 be reconsidered and withdrawn and the instant claims be examined in one application. However, should the restriction be maintained, Applicants request rejoinder of the claims of group II with claims 14-15 of group I (process of making polypeptides) once the claims of group II are found allowable. In light of the decisions in *In re Ochiai*, 71 F.3d 1565 (Fed. Cir. 1995) and *In re Brouwer*, 77 F.3d 422 (Fed. Cir. 1996), a notice was published in the Official Gazette which set forth new guidelines for the treatment of product and process claims. See 1184 OG 86 (March 26, 1996). Specifically, the notice states that:

in the case of an elected product claim, rejoinder will be permitted when a product claim is found allowable and the withdrawn process claim depends from or otherwise includes all the limitations of an allowed product claim.

Id. Accordingly, if claims of group II are found allowable, Applicants respectfully request that the claims 14-15 of group I be rejoined and examined for patentability.

Applicants retain the right to petition from the restriction requirement under 37 C.F.R. § 1.144 should it be made final. Applicants respectfully request that the above-made remarks be entered and made of record in the file history of the instant application.

Applicants point out that claims 1-13 and 16-24 have been canceled and that claims 25-46 are directed to subject matter falling within the ambit of group II as cast by the Examiner.

Conclusion

In view of the foregoing remarks, Applicants believe that this application is now in condition for substantive examination. The Examiner is invited to call the undersigned at the phone number provided below if any further action by applicant would expedite the examination of this application.

Finally, if there are any fees due in connection with the filing of this paper, please charge the fees to our Deposit Account No. 08-3425. If a fee is required for an extension of time under 37 C.F.R. § 1.136 not accounted for above, such an extension is requested and the fee should also be charged to our Deposit Account.

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Respectfully submitted,

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